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10/649,719

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/649,719	Applicant(s) NAKAJIMA, KENJI	
	Examiner ANN Y. LAM	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 15, 16 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 15, 16 and 18-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-4, 15, 16 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/692,011, in view of Decker et al., 4,230,683.

Application No. 10/692,011 recites the limitations substantially as claimed (see claims 1-9), except for the receptor being labeled with an enzyme, nor that the enzyme is part of an enzyme-labeled antibody wherein the enzyme-labeled antibody is subjected to

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specific binding with the labeled receptor. Decker et al. however teach this specific type of assay.

Decker et al. teach an improvement in an immunoassay comprising the steps of reacting an antigen bound to a solid support with a hapten/conjugated antibody to the antigen, further reacting hapten conjugated antibody bound to the solid support with labeled anti-hapten antibody and determining the labeled antibody bound to the solid support (col. 1, lines 59-64). Decker et al. teach that the invention makes use of hapten conjugated antibodies to amplify antigenicity of the bound antibody. Each hapten conjugated antibody will have several hapten molecules bound thereto providing for multiplication of the antigenic reactivity (col. 2, lines 59-63). Moreover, Decker et al. teach that methods for directly or indirectly binding antigens or antibodies to be detected to a solid support are well known (col. 1, lines 7-11, and lines 38-40). Decker et al. also teach that the use of labeled antibodies (i.e., labeled with enzymes for example) in solid phase immunoassay is well known (col. 2, lines 43-45).

As to claim 19, Applicant claims in the present application that the liquid containing the labeled receptor is caused to flow across the adsorptive regions at a different time from when the enzyme-labeled antibody is caused to flow across the adsorptive regions. While Decker et al. disclose the reagents mentioned above and performing the assay by allowing the reagents to react respectively with each other, there is no specific disclosure of flowing the two liquids mentioned above at different times. However, it is predictable by the skilled artisan that the reagents mentioned above may be flowed at different times, as such flowing will also allow for the reactions

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to occur and thus the assay to be performed. Such predictability renders the steps obvious.

It would have been obvious to one ordinary skill in the art at the time the invention was made to perform the Decker et al. immunoassay using the invention claimed by Application No. 10/692,011 because Decker et al. teach that the immunoassay as disclosed, including use of hapten/conjugated antibody, provides an improvement of the immunoassay because it amplifies the antigenic reactivity of the immunoassay. One of ordinary skill in the art would be motivated to utilize the improved immunoassay as the particular assay performed using the method recited in Application No. 10/692,011 for its amplified detection, as would be desirable for more accurate results.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 15, 18 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al., 6,716,629, in view of Decker et al., 4,230,683, and Rubenstein et al., 3,875,011, and in light of Patel et al., 5,260,222.

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As to claims 1, 3, 15, 18, 21-23 and 25-27, Hess et al. teach the step of providing a platen (biochemical analysis unit) with an array of through-holes traversing the platen, the through-holes having a three-dimensional hydrophilic scaffold placed therein (i.e., porous adsorptive regions comprising holes filled with a porous material), and wherein the scaffold is activated to couple biological materials within the holes (i.e., bound receptors). See column 13, lines 65 to column 14, line 3; and column 20, lines 45-62). Spotting materials onto the through holes is disclosed (see for example col. 43, lines 23-24.) Detection of antibodies using bound antigens via elisa is disclosed (col. 59, lines 43-65, disclosing antibody conjugated to horseradish peroxidase and use of the enzyme substrate for detection.) In addition, Hess et al. teach that platen can be used to screen for ligands by affinity (i.e., performing a specific binding detection process) by performing the step of applying pressure across the platen to create a flow of sample through the array of through-holes, where the sample is a second set of reagents that can react with reagents already loaded into the through-holes (i.e., forcibly causing a ligand to flow through the holes; ligand subject to specific binding with bound receptors. See column 35, lines 32-42; and column 28, lines 16-22. Hess et al. also teach that specific binding can be detected by applying a radiolabeled sample protein to an array of 100,000 different proteins in the platen, applying a wash step, and then detecting the presence of radiolabeled protein by a phosphor-imaging system (i.e., detecting the receptor by the utilization of a labeling substance; labeled receptor). See column 55, line 64 to column 56, line 7. Hess et al. also teach that all through-holes can be loaded

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(i.e., through each of the holes.) See column 7, lines 14-15. As to claims 25 and 26, the platen is a plate-like member.

However, the specific assay recited by Applicant is not disclosed by Hess et al. (i.e., an assay using a labeled ligand or receptor in addition to an enzyme labeled antibody.) Such an assay however is known in the art, as shown by Decker et al.

Decker et al. teach an improvement in an immunoassay comprising the steps of reacting an antigen bound to a solid support with a hapten/conjugated antibody to the antigen, further reacting hapten conjugated antibody bound to the solid support with labeled anti-hapten antibody and determining the labeled antibody bound to the solid support (col. 1, lines 59-64). Decker et al. teach that the invention makes use of hapten conjugated antibodies to amplify antigenicity of the bound antibody. Each hapten conjugated antibody will have several hapten molecules bound thereto providing for multiplication of the antigenic reactivity (col. 2, lines 59-63). Moreover, Decker et al. teach that methods for directly or indirectly binding antigens or antibodies to be detected to a solid support are well known (col. 1, lines 7-11, and lines 38-40). Decker et al. also teach that the use of labeled antibodies (i.e., labeled with enzymes for example) in solid phase immunoassay is well known (col. 2, lines 43-45).

The hapten/conjugated antibody is equivalent to the claimed labeled receptor. The labeled antihapten antibody is equivalent to the claimed labeled antibody. Decker et al. teach in column 1, lines 49-53 that enzymes [labels] such as catalase, peroxidase .beta.-glucouronidase, glucose-6-phosphate dyhydrogenase, urease, and glucoseoxidase are conveniently linked to antibodies by art recognized techniques such

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as that in patent number 3,875,011 [to Rubenstein et al.] While Decker et al. do not actually disclose that a substrate is added for reaction with the enzyme for its detection, this is disclosed in the patent to Rubenstein et al. in column 21, lines 46-60. Thus, use of the enzyme substrate as is well known in the art, and as shown by Rubenstein et al., would have been obvious to the skilled artisan in order to detect the enzyme label.

The skilled artisan would have recognized that the Hess et al. device and method can be used to perform a variety of assays including the one as described above, since it merely involves providing the specific reagents to the Hess et al. device.

As to claims 2 and 4, Hess et al. do not disclose ceasing flow of the liquid containing enzyme-labeled antibody for a period longer than which it was forcibly caused to flow. However it is predictable by the skilled artisan that ceasing of flow for a period longer than the period for which it flowed further allows for the reaction to reach completion or equilibrium, as would be desirable in performing a detection assay, and such basic concept would have been recognized by the skilled artisan.

As to claim 24, the platens with through-holes may be stacked (col. 14, lines 51-67.) (The upper platen thus inherently acts to filter.)

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al., 6,716,629, in view of Decker et al., 4,230,683, and Rubenstein et al., 3,875,011, and

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in light of Patel et al., 5,260,222, as applied to claim 3 above, and further in view of Shipwash, 6,846,638.

Regarding claim 16, Applicant recites that the method further comprises photoelectrically detecting the bound labeled receptor, which is not disclosed by Decker et al. This is not disclosed by Hess et al.

However, Shipwash disclose that labels for use in the invention include enzymes that produce luminescent or electrogenic products (col. 60, lines 6-21), and that the labels will be detected in a manner appropriate to their nature, and optical detection methods including CCD cameras are commonly employed for detection (col. 32, lines 49-57). It would have been obvious to one of ordinary skill in the art to utilize an enzyme label that produces luminescent or electrogenic products as the enzyme label in the Hess et al. method, because Hess et al. do not limit the label to any particular label but rather disclose that enzyme labels well known in the art may be used, and Shipwash disclose that such known enzyme labels are those that produce luminescent or electrogenic products.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al., 6,716,629, in view of Decker et al., 4,230,683, and Rubenstein et al., 3,875,011, and in light of Patel et al., 5,260,222, as applied to claim 3 above, and further in view of Conrad et al., 20020165373.

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Hess et al. do not disclose fixing the receptors or ligands to each of the plurality of porous adsorptive regions using ultraviolet light.

However, Conrad et al. disclose cross-linking DNA to a membrane using a UV crosslinker (paragraph 0176). The skilled artisan would have recognized that a cross-linker generally crosslinks any of a variety of biomolecules to a substrate, such as the biomolecules as discussed above in claim 3 to the Hess et al. porous regions. The skilled artisan would have recognized the desirability of immobilizing the probe reagents to the membrane by such crosslinking to prevent them from washing away with the flowed reagents.

Claim 1-4, 15, 18, 19, 21-24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Damme et al., 6,855,539, in view of Decker et al., 4,230,683, and Rubenstein et al., 3,875,011, and in light of Patel et al., 5,260,222.

As to claims 1, 3, 15 and 18, van Damme et al. disclose a device for performing an assay. The device comprises a substrate having interconnected channels, wherein the channels open out on a surface for sample application. The channels in at least one area of the surface for sample application are provided with a first binding substance capable of binding to an analyte, wherein the substrate is an electrochemically manufactured metal oxide membrane and the first binding substance is within the

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interconnected channels in the substrate. In some embodiments, the first binding substance is covalently bound to the substrate. Column 2, lines 41-52.

Van Damme et al. also disclose a method of manufacturing the device, include using ink-jet technology to apply the first binding substance. Column 2, line 63 to column 3, line 4. Providing the first binding substance in an array of a plurality of areas is also disclosed. Column 7, lines 41-56. Spotting the membrane to transfer materials to the membrane is disclosed as well. Column 11, lines 41-55, and column 13, line 66 to column 14, line 3. It is noted that the array of plurality of areas is equivalent to Applicant's claimed plurality of porous adsorptive regions. The membrane is equivalent to Applicant's biochemical analysis unit comprising a plurality of adsorptive regions.

Also disclosed is a method for the detection of an analyte in a sample, the method comprising the steps of a) contacting the sample with any of the above-described devices, b) allowing binding to take place between the first binding substance and the analyte to be detected, and c) detecting whether binding has occurred between first binding substance and the analyte. In certain aspects of these embodiments, step a) and b) is repeated at least once before performing step c), preferably by first performing step a) and b) by passing the sample through the membrane in one direction perpendicular to the surface of the membrane, then repeating steps a) and b) by passing the sample through the membrane in the opposite direction. Column 3, lines 15-27.

Control of flow is provided by an automated Hamilton dispenser. Column 12, lines 27-28.

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A variety of assays can be performed using the device. Van Damme et al. disclose an example wherein a probe labeled with horseradish peroxidase enzyme is allowed to interact with the membranes. Column 12, lines 35-48. A enzyme immunoassay in a sandwich format is also disclosed. Column 13, lines 55-60.

However, the specific assay recited by Applicant is not disclosed by van Damme et al. Such an assay however is known in the art, as shown by Decker et al.

Decker et al. teach an improvement in an immunoassay comprising the steps of reacting an antigen bound to a solid support with a hapten/conjugated antibody to the antigen, further reacting hapten conjugated antibody bound to the solid support with labeled anti-hapten antibody and determining the labeled antibody bound to the solid support (col. 1, lines 59-64). Decker et al. teach that the invention makes use of hapten conjugated antibodies to amplify antigenicity of the bound antibody. Each hapten conjugated antibody will have several hapten molecules bound thereto providing for multiplication of the antigenic reactivity (col. 2, lines 59-63). Moreover, Decker et al. teach that methods for directly or indirectly binding antigens or antibodies to be detected to a solid support are well known (col. 1, lines 7-11, and lines 38-40). Decker et al. also teach that the use of labeled antibodies (i.e., labeled with enzymes for example) in solid phase immunoassay is well known (col. 2, lines 43-45).

The hapten/conjugated antibody is equivalent to the claimed labeled receptor. The labeled antihapten antibody is equivalent to the claimed labeled antibody. Decker et al. teach in column 1, lines 49-53 that enzymes [labels] such as catalase, peroxidase .beta.-glucouronidase, glucose-6-phosphate dyhydrogenase, urease, and

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glucoseoxidase are conveniently linked to antibodies by art recognized techniques such as that in patent number 3,875,011 [to Rubenstein et al.] While Decker et al. do not actually disclose that a substrate is added for reaction with the enzyme for its detection, this is disclosed in the patent to Rubenstein et al. in column 21, lines 46-60. Thus, use of the enzyme substrate as is well known in the art, and as shown by Rubenstein et al., would have been obvious to the skilled artisan in order to detect the enzyme label.

The skilled artisan would have recognized that the van Damme et al. device and method can be used to perform a variety of assays including the one as described above, since it merely involves providing the specific reagents to the van Damme et al. device.

As to claims 2 and 4, van Damme et al. do not disclose ceasing flow of the liquid containing enzyme-labeled antibody for a period longer than which it was forcibly caused to flow. However it is predictable by the skilled artisan that ceasing of flow for a period longer than the period for which it flowed further allows for the reaction to reach completion or equilibrium, as would be desirable in performing a detection assay, and such basic concept would have been recognized by the skilled artisan.

As to claim 19, Applicant claims that the liquid containing the labeled receptor is caused to flow across the adsorptive regions at a different time from when the enzyme-labeled antibody is caused to flow across the adsorptive regions. While Decker et al. disclose the reagents mentioned above and performing the assay by allowing the reagents to react respectively with each other, there is no specific disclosure of flowing the two liquids mentioned above at different times. However, it is predictable by the

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skilled artisan that the reagents mentioned above may be flowed at different times, as such flowing will also allow for the reactions to occur and thus the assay to be performed. Such predictability renders the steps obvious.

As to claims 21 and 27, van Damme et al. disclose using the membrane in a flow through cell (col. 10, lines 58-61.) While van Damme et al. do not explicitly disclose that the membrane (equivalent to Applicant's biochemical analysis unit) is *fixed* in the flow through cell and remains fixed during the assay procedures, the skilled artisan would have understood that this is the case, as would be necessary for allowing the fluid to flow perpendicular to the membrane as disclosed by van Damme et al.

As to claim 22, it is understood that the reagents enter the flow through cell on the same side. While it is disclosed that the contacting steps may be repeated at least once by, for example, passing the reagents through the membrane in one direction and then in the opposite direction (col. 3, lines 15-27), it is understood that the reagents may then exit the flow through cell, on the opposite side of the membrane from the side which it entered the flow through cell, since it is generally understood that flow through cells allow for materials to flow from one end and exit at another end.

As to claim 23, Applicant essentially recites a washing step to remove unbound materials. A washing step is well known in the assay art for removal of unbound materials, such as unbound labeled materials, so that the detection step detects only the bound labeled materials. Such a step is well within the skills of the ordinary artisan.

As to claim 24, while it is not specifically disclosed by van Damme et al. that the reagent molecules or complexes are smaller than the pore diameter of the membrane, it

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is understood that such is encompassed by the disclosed invention, particularly since the purpose of flowing materials in the opposite direction is to allow for binding to take place, i.e., for contact between the reagents in the flowed fluid and the reagents on the membrane (col. 3, lines 15-27.)

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Damme et al., 6,855,539, in view of Decker et al., 4,230,683, and Rubenstein et al., 3,875,011, and in light of Patel et al., 5,260,222, as applied to claim 3 above, and further in view of Shipwash, 6,846,638.

As noted earlier, the labeled receptor is disclosed by Decker et al., the label being disclosed in general as those well known in the art, for example enzymes and fluorescent chemicals, (see col. 2, lines 43-45; and see also col. 1 lines 49-52). It is also noted that van Damme et al. disclose using the membrane in a flow through cell (col. 10, lines 58-61.) It is also disclosed that after each passage of the sample, the fluorescence was recorded with a fluorescent microscope and digitized with a CCD camera. The image formation was converted into spot intensity values using a software image analysis package. Column 15, lines 10-15.

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Regarding claim 16, Applicant recites that the method further comprises photoelectrically detecting the bound labeled receptor, which is not disclosed by Decker et al. This is not disclosed by van Damme et al.

However, Shipwash disclose that labels for use in the invention include enzymes that produce luminescent or electrogenic products (col. 60, lines 6-21), and that the labels will be detected in a manner appropriate to their nature, and optical detection methods including CCD cameras are commonly employed for detection (col. 32, lines 49-57). It would have been obvious to one of ordinary skill in the art to utilize an enzyme label that produces luminescent or electrogenic products as the enzyme label in the Decker et al. method, because Decker et al. do not limit the label to any particular label but rather disclose that enzyme labels well known in the art may be used, and Shipwash disclose that such known enzyme labels are those that produce luminescent or electrogenic products. Moreover, the skilled artisan would utilize the CCD camera for detection, as taught by Shipwash, because Shipwash teaches that the labels will be detected in a manner appropriate to their nature and the skilled artisan would recognize that the luminescent product of the enzyme label is detectable by a CCD camera. (It is noted that Applicant's specification disclose that a CCD camera is utilize for photoelectrically detecting.)

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Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Damme et al., 6,855,539, in view of Decker et al., 4,230,683, and Rubenstein et al., 3,875,011, and in light of Patel et al., 5,260,222, as applied to claim 3 above, and further in view of Conrad et al., 20020165373.

Van Damme et al. disclose the membrane as discussed above. However, Van Damme et al. do not disclose fixing the receptors or ligands to each of the plurality of porous adsorptive regions using ultraviolet light.

However, Conrad et al. disclose cross-linking DNA to a membrane using a UV crosslinker (paragraph 0176). The skilled artisan would have recognized that a cross-linker generally crosslinks any of a variety of biomolecules to a substrate, such as the biomolecules as discussed above in claim 3 to the van Damme et al. membrane. The skilled artisan would have recognized the desirability of immobilizing the probe reagents to the membrane by such crosslinking to prevent them from washing away with the flowed reagents.

Response to Arguments

Applicant's arguments filed November 10, 2008 have been fully considered. Applicant has amended the claims and added some new claims. In particular, Applicant has amended the claims to recite that the reagents are flowed in a direction transverse to a surface of the biochemical analysis unit. Such amendment was also proposed in

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the interview of November 5, 2008. The amendment has overcome the Hudak et al. reference applied in the previous Office action, and thus the grounds for rejection based on Hudak et al. as the primary reference has been withdrawn. However, the amended claims are not patentable over the newly cited references (the Hess et al. and van Damme et al. patents).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641